REMARKS

Applicant respectfully requests reconsideration. Claims 37, 39-56 were previously pending in this application. Claim 37 is amended herein. As a result, claims 37, 39-56 are still pending for examination with claim 37 being an independent claim. No new matter has been added.

Rejection Under 35 U.S.C. 112

Claims 37 and 39-56 have been rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. According to the Examiner, the claims are directed to a method for stimulating subjects responsive to a vaccine comprising administering an immunostimulatory oligonucleotide adjuvant as a vaccine adjuvant with the vaccine to the subject to stimulate the subject's response to the vaccine, wherein the immunostimulatory oligonucleotide comprises a phosphate backbone modification and an unmethylated cytosine-guanine dinucleotide. Dependent claims further claim phosphate backbone modifications, modes of administration, and nucleic acid delivery systems. Further, according to the Examiner, the claims do not define the structure of the immunostimulatory oligonucleotides and it is not clear if the claims or specification give structure and a function of the immunostimulatory oligonucleotides, as required by the written description guidelines.

Applicant respectfully traverses. Applicant has amended claim 37 and included the limitation "wherein the oligonucleotide is at least eight nucleotides in length." Support for this amendment can be found in the written description at least on page 13, lines 19-20.

As stated by the Examiner, the structure is defined in that the immunostimulatory oligonucleotide comprises a phosphate backbone and an unmethylated cytosine-guanine dinucleotide. Applicant provides at least 27 different oligonucleotides that comprise an unmethylated cytosine-guanine dinucleotide (See Table 1 on pages 14-15). Among the features that the tabulated oligonucleotides have in common is that they provoke an immune response consistent with a vaccine adjuvant and that they comprise an unmethylated cytosine-guanine dinucleotide. A claim containing the elements "an oligonucleotide comprising an unmethylated cytosine-guanine dinucleotide" functionally coupled to "adjuvant activity" is therefore supported by written

description. According to the Examiner, "other" structural components are missing from the claimed invention. However, the "other" structural components are described in the claim, namely "an oligonucleotide". Written description support for an "oligonucleotide" is provided at least on page 9, lines 16-25. In addition, a person of ordinary skill in the art is familiar with the term "oligonucleotide". While the oligonucleotides claimed by the invention can comprise additional structural features, these features are irrelevant to the current claimed invention. A person of ordinary skill in the art will thus appreciate that the Applicants were in possession of the claimed invention at the time of filing, without the need for the definition of any "other" structural components.

According to the Examiner, "neither the specification nor the claims disclose the structure of the immunostimulatory oligonucleotide set forth in the claims. The recitation of 'comprising' indicates that there are other structural components to the claimed immunostimulatory oligonucleotides and that these structures of the additional nucleic acids or components are not known." However, the term "comprising" merely means that the claim is not limited to the specific elements recited. The MPEP states (§2111.03) "'Comprising' is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim *Genetech, Inc. v. Chiron Corp.*, 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997)." All the essential elements, namely an unmethylated cytosine-guanine dinucleotide are provided in the claim. While other elements may be added, these elements are not essential to arrive at the claimed invention. For instance, if the oligonucleotide comprises six or eight guanines in addition to the unmethylated cytosine-guanine dinucleotide is irrelevant to the claimed invention.

The Examiner also states that "a biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes". However, Applicants disclose a correlation between function and structure. Applicants are not claiming "any nucleotide comprising an unmethylated cytosine-guanine dinucleotide", but are claiming the use of an oligonucleotide comprising an unmethylated cytosine-guanine dinucleotide as vaccine adjuvant. Thus, Applicants disclose a correlation between function and

structure (i.e. a nucleotide comprising an unmethylated cytosine-guanine dinucleotide is a vaccine adjuvant) and this correlation is supported in the written description (See e.g. Table 1)

The Examiner also refers to the written description requirements set forth under 35 USC §112, first paragraph, and states that "the specification must describe at least a substantial number of the members of the claimed genus, or alternatively describe a representative member of the claimed genus, which shares a particularly defining feature common to at least a substantial number of the members of the claimed genus, which would enable the skilled artisan to immediately recognize and distinguish its members from others, so as to reasonably convey to the skilled artisan that Applicant has possession of the claimed invention". The specification clearly meets these requirements. Applicants describe at least 27 members of the claimed genus (See Table 1), which share a particular defining feature (an unmethylated cytosine-guanine dinucleotide). A skilled artisan would immediately recognize and distinguish members of the claimed genus from others, namely by evaluating if the oligonucleotide comprises an unmethylated cytosine-guanine dinucleotide. If the oligonucleotide comprises an unmethylated cytosine-guanine dinucleotide it is a member of the claimed genus.

The MPEP §2163.02 states "An objective standard for determining compliance with the written description requirement is 'does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed' *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ 1614, 1618 (fed. Cir. 1989)". "To satisfy the written description requirement, an application most convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever now is claimed (*Vas-Cath, Inc. v.Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Circ. 1991)". To explain the term "possession" the Examiner quotes from The Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, paragraph 1, "Written Description" requirement (66 FR 1099-1111, January 5, 2001), " Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention". The claimed invention provides detailed guidelines, which allow a person of ordinary skill in the art to practice the current invention (See Table 1 and the

working examples). In addition, the written description provides distinguishing identifying characteristics (namely, does the oligonucleotide comprise an unmethylated cytosine-guanine dinucleotide), thereby conveying that Applicant was in possession of the invention.

Furthermore, according to the Examiner, "because the claims encompass a genus of variant species, an adequate written description of the claimed invention must include sufficient description of at least a representative number of species by actual reduction to practice". As already stated earlier, Applicant has shown reduction to practice for at least 27 species, i.e., a representative number of species.

Applicant has shown possession of the claimed invention. Applicant therefore satisfies the requirements for written description under 35 USC §112, first paragraph. Accordingly, withdrawal of the rejection is respectfully requested.

CONCLUSION

A Notice of Allowance is respectfully requested. The Examiner is requested to call the undersigned at the telephone number listed below if this communication does not place the case in condition for allowance.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 23/2825.

Dated: May 18, 2007

Respectfully submitted,

By _____

Helen C. Lockhart
Registration No.: 39,248
WOLF, GREENFIELD & SACKS, P.C.
Federal Reserve Plaza
600 Atlantic Avenue
Boston, Massachusetts 02210-2206
(617) 646-8000